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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,561	07/11/2003	Frederick M. Enright	026039-0362798	8244

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EXAMINER	
DANG, IAN D	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
10/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/617,561	ENRIGHT ET AL.	
	Examiner	Art Unit	
	IAN DANG	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,11-14,17,127 and 131-133* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1-8,11-14,17,31-41,48,59-70,73-76,79,83,86,87,105-114,116,118,120,122-128 and 131-133.
Continuation of Disposition of Claims: Claims withdrawn from consideration are 31-41,48,59-70,73-76,79,83,86,87,105-114,116,118,120 and 122-128.

DETAILED ACTION

Status of Application, Amendments and/or Claims

The amendment of 11/07/2007 has been entered in full. Claims 9-10, 15-16, 18-30, 42-47, 49-58, 71-72, 77-78, 80-82, 84-85, 88-104, 115, 117, 119, 121, 129-130 have been cancelled and claim 1 has been amended.

This application contains claims 31-41, 48, 59-70, 73-76, 79, 83, 86-87, 105-114, 116, 118, 120, 122-128 drawn to an invention nonelected with traverse in the reply filed on 02/23/2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-8, 11-14, 17, 127, and 131-133 are under examination.

Specification

The disclosure is objected to because of the following informalities:

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Appropriate correction is required.

Rejections Maintained

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined

application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8, 11-14, 17, and 127 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 12, 14, 16, 18, 22, 24, 32, and 40 of U.S. Patent No. 6,635,740.

Although Applicants did not address this rejection in the response filed 11/07/2007, the rejection of claims 1-8, 11-14, 17, and 127 is maintained, since the Examiner has not been able to locate any Terminal Disclaimer. At page 3 of the response filed 02/14/2007, Applicant indicates that a Terminal Disclaimer is already of record in this application having been filed on July 11, 2003. However, upon reviewing the record of the instant application, the Examiner has not been able to locate any Terminal Disclaimer or fees associated with such. The Examiner requests that Applicant provide the submission date for the alleged Terminal Disclaimer.

35 USC § 112, First paragraph (Written Description)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 131-133 remain rejected under 35 U.S.C. 112, First paragraph (Written Description) as failing to comply with the written Description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

At pages 11-16 of the response, Applicants have provided numerous case laws and references to satisfy the written description requirements regarding hormone analogues and lytic peptides of the claimed invention.

Although Applicant's response and arguments filed on 11/07/2007 have overcome the rejection of claims 1-8, 11-14, 17, 127 under 35 USC 112, First paragraph (Written Description) regarding hormone analogues and lytic peptides of the claimed invention, the rejection is maintained for acute-phase responsive promoter, bacterial transposase and transposon insertion sequences recited in claims 131-133.

Since the Examiner has concerns about Applicants' recitation regarding acute-phase responsive promoter, bacterial transposase and transposon insertion sequences being art accepted or that these promoters exist, the Examiner requests that Applicants support the assertion that their claimed invention is well known in the art with references disclosing acute-phase responsive promoter, bacterial transposase and transposon insertion sequences. Without providing such disclosures or references, Applicants would not satisfy the written description requirements for (i) a gene linked to an acute-phase responsive promoter, and (ii) a vector for inserting a gene into a chromosome of a eukaryotic cell comprising (a) gene encoding a bacterial transposase, (b) two transposon insertion sequences recognized by the transposase, (c) a gene wherein the gene is between the two transposon insertion sequences; and (d) a

promoter that is operably linked to said transposase gene.

Claim Rejections - 35 USC § 112 (Enablement)

Claims 131-133 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a gene encoding a peptide comprising bLH or beta subunit of gonadotropin-releasing hormone, lamprey III luteinizing hormone releasing hormone, beta chain of luteinizing hormone, luteinizing hormone, chorionic gonadotropin, the beta subunit of chorionic gonadotropin, follicle stimulating hormone, melanocyte-stimulating hormone, or somatostatin and analogues of these hormones in the first domain and a lytic peptide consisting of cecropin peptide, melittin peptide, defensin peptide, magainin peptide, or sarcotoxin peptide and analogues of these peptides in the second domain, does not reasonably provide enablement for (i) a gene linked to an acute-phase responsive promoter, and (ii) a vector for inserting a gene into a chromosome of a eukaryotic cell comprising (a) gene encoding a bacterial transposase, (b) two transposon insertion sequences recognized by the transposase, (c) a gene wherein the gene is between the two transposon insertion sequences; and (d) a promoter that is operably linked to said transposase gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

At page 17 of the response, Applicants argue that except for promoters (acute phase responsive promoter), transposon insertion sequences and transposon genes, all grounds for rejection set forth in the Office Action relate to making and using the peptides, not the genes. Consequently, the grounds for rejection set forth in the Office Action relating to making and using peptides are not relevant to the claims.

In addition, Applicants argue that those producing genes by recombinant methods was routine and well within the capability of one skilled in the art at the time of the invention. Thus, if the skilled artisan wished to make genes that encode peptide variants undue experimentation would not be required.

Furthermore, the claimed genes could be expressed in cells in order to produce encoded peptide using a cell based expression system or in vitro translation system to produce peptide variants. Thus, if the skilled artisan wished to use the claimed genes to produce peptide variants undue experimentation would not be required.

Finally, Applicants argue that undue experimentation would not be required to identify promoters, transposon insertion sequences, and transposon genes that have activity, given that assays for determining such activities were known in the art at the time of the invention. Consequently, the skilled artisan need not "predict" in advance genes that encode peptide variants or promoters, transposon insertion sequences and transposon genes that have activity. Instead, the skilled artisan would merely screen peptide variants or promoters and transposon insertion sequences using an appropriate activity assay.

Although Applicant's response and arguments filed on 11/07/2007 have overcome the rejection of claims 1-8, 11-14, 17, 127, 131-133 under 35 USC 112, First paragraph (Enablement) regarding hormone analogues and lytic peptides analogues of the claimed invention, the rejection is maintained for acute-phase responsive promoter, bacterial transposase and transposon insertion sequences.

Although Applicants disclose references to meet the enablement requirements for hormone analogues and lytic peptides analogues of the claimed invention (see pages 11-16 of the response filed 11/07/2007), the specification does not provide any guidance regarding

acute-phase responsive promoter, bacterial transposase and transposon insertion sequences of the claimed invention.

Since the Examiner has concerns about Applicants' recitation regarding acute-phase responsive promoter, bacterial transposase and transposon insertion sequences being art accepted or that these promoters exist, the Examiner requests that Applicants support the assertion that their claimed invention is well known in the art with references disclosing acute-phase responsive promoter, bacterial transposase and transposon insertion sequences as well known in the art. Without providing such references, Applicants' claimed invention regarding (i) a gene linked to an acute-phase responsive promoter, and (ii) a vector for inserting a gene into a chromosome of a eukaryotic cell comprising (a) gene encoding a bacterial transposase, (b) two transposon insertion sequences recognized by the transposase, (c) a gene wherein the gene is between the two transposon insertion sequences; and (d) a promoter that is operably linked to said transposase gene would require undue experimentation.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IAN DANG whose telephone number is (571)272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang
Patent Examiner
Art Unit 1647
October 22, 2008

/Robert Landsman/
Primary Examiner, Art Unit 1647